

**Appl. No.** : 10/670,999  
**Filed** : September 25, 2003

### **REMARKS**

The Office Action of May 22, 2007 was based on pending Claims 1-17 and 26. Claim 26 is amended by this paper and thus Claims 1-17 and 26 remain pending. The Applicants respectfully request reconsideration of the subject application.

In the Office Action, the Examiner rejects Claim 26 under 35 U.S.C. § 102(e) as being anticipated by Hole et al. (U.S. Publication No. 2004/0081580). The Applicants note that Hole et al. describes systems for systemic delivery of a treatment gas, nitric oxide, for treatment of infection and reduction of pathogens. While Hole et al. does disclose a treatment device including an oxygenator, at least one being a catheter, and at least one arterial catheter, Hole et al. fails to disclose an analysis gas delivery line particularly wherein the analysis gas is selected to indicate leakage between a systemic circulation and an artificial circulation. Rather, the gas source 7 indicated by the Examiner and further connected to tubing 9 provides a treatment gas, nitric oxide, not an analysis gas as in the Applicants' claimed invention. As Hole et al. fails to disclose each and every aspect of the Applicants' claimed invention as recited in Claim 26, the Applicant believes that Hole et al. does not anticipate the Applicants' claimed invention of Claim 26 under the requirements of 35 U.S.C. § 102(e). The Applicants respectfully request that the rejection be withdrawn.

The Examiner also rejects Claims 1-6, 9, 11, 15, 16, and 26 under 35 U.S.C. § 103(a) as being unpatentable over Allers et al. (U.S. Patent No. 6,287,273). The Applicants have carefully reviewed the Allers et al. '273 reference and notes that Allers et al. describes a perfusion system for isolated perfusion of an organ. A leakage of the Allers system towards the systemic circulation can be detected by adding a substance, such as a dye or a radioactive marker to the isolated circulation. The substance can be detected in the systemic circulation in case of leaks. Allers et al. further describes analysis of the substance in the systemic blood circulation or in blood samples.

However, the Applicant strongly believes that the skilled artisan would not be motivated to modify the Allers et al. system to use gas as an indicating substance rather than the described dye or radiological marker. Such a modification of Allers would result in analysis of a gaseous substance in the systemic blood circulation. The Applicants note the difficulty of performing such a measurement in the systemic circulation as a gaseous substance would undergo gas

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exchange in the lungs and be relatively rapidly eliminated. Gaseous substances entrained in the systemic blood circulation would not be readily identified by imaging whereas the carrier medium dyes described by Allers et al. can be readily identified via imaging. Similarly, whereas the extracorporeal meter capable of measuring radioactivity in a blood vessel described by Allers et al. could readily identify radiological markers, such extracorporeal sensing of gaseous substances entrained in the systemic circulation is more difficult. Further, the Applicants note the need to avoid creating bubbles of a gaseous substance whereas this concern is significantly less using liquid or solid indicating substances as disclosed by Allers et al. Thus, the Applicants believe that the subject matter of Claims 1-6, 9, 11, 15, 16, and 26 as currently amended, are not obvious to the skilled artisan in light of the Allers et al. reference. The Applicants respectfully request that the rejection of Claims 1-6, 9, 11, 15, 16, and 26 be withdrawn.

The Examiner further rejects Claims 5 and 15 under 35 U.S.C. § 103(a) as being unpatentable over Allers et al. in view of Burton (WO 01/43804). The Applicants have reviewed the Burton reference and notes that Burton describes a respiration mask with sensors for use when artificially supporting the breathing of patients. Burton is particularly directed towards controlling the breathing functions of the patients. However, Burton et al. only describes that anesthetic gas is being delivered to the patient by means of the respiration mask and that the amount of delivered anesthetic gas can be controlled. Burton does not describe or suggest detection of gaseous substances particularly for detection of leakage between an isolated circulation and a systemic circulation.

The Applicants believe that the skilled artisan starting from the Allers et al. disclosure and further taking the disclosure of Burton into account would arrive at a system including a respiratory mask for applying an anesthetic gas to a patient with means for controlling the amount of anesthetic gas delivered with the perfusion circuit disclosed by Allers et al. As previously indicated, the Applicants believe that the skilled artisan would not modify Allers et al. to use a gaseous substance for detection of leakage between an isolated circulation and a systemic circulation and thus a combination of the two references would simply use the modified system to detect and monitor the gases used for artificial respiration, for example, including an anesthetic gas. Any teachings of leakage in Burton refer to leakage between the treated patient and the artificial respiration device, such as the respiration mask. Burton does not teach

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detecting a leakage between isolated circuits. The Applicant thus believes that Claims 5 and 15 are patentable under the requirements of 35 U.S.C. § 103(a) over Allers et al. in view of Burton and respectfully request that the rejection of these claims be withdrawn.

*No Disclaimers or Disavowals*

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

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### SUMMARY

The Applicant believes that the subject application is in a condition ready for allowance and respectfully requests prompt issuance of a notice of allowability. The Applicant believes that this paper is fully responsive to the objections and rejections made by the Examiner in the Office Action, however should there remain any further impediments to the allowance of this application that might be resolved by telephone conference the Examiner is respectfully requested to contact the Applicant's undersigned representative at the indicated telephone number.

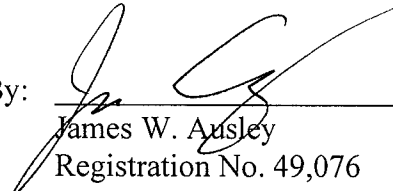
Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

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